

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

AUBREY LEE CHRISTIAN,

Plaintiff,

CASE NO. 12-CV-11113

v.

DISTRICT JUDGE DENISE PAGE HOOD
MAGISTRATE JUDGE CHARLES E. BINDER

ASTRAZENECA LP, SANDRA
VONDEREMBSE M.D., and
MDOC HEALTH SERVICES
DIVISION,

Defendants.

**MAGISTRATE JUDGE’S REPORT AND RECOMMENDATION
ON DEFENDANT ASTRAZENECA’S MOTION TO DISMISS**

(Doc. 12)

**AND RECOMMENDING *SUA SPONTE* DISMISSAL OF
CASE IN ITS ENTIRETY**

I. RECOMMENDATION

For the reasons set forth below, **IT IS RECOMMENDED** that Defendant AstraZeneca’s Motion to Dismiss be **GRANTED** and that the case be *sua sponte* **DISMISSED** in its entirety.

II. REPORT

A. Introduction & Procedural History

Plaintiff Aubrey Lee Christian is a state prisoner who is incarcerated at the Lakeland Correctional Facility in Coldwater, Michigan. This case began in November 2011, when Plaintiff filed a *pro se* “Complaint for Negligence” against Defendant AstraZeneca Pharmaceuticals LP (“AstraZeneca”) in the United States District Court for the Middle District of Florida. (Doc. 1.) The two-page complaint alleged that AstraZeneca “had a product on the market, a drug known as SEROQUEL, which caused the plaintiff, Aubrey Lee Christian, to develop irreversible side effects, and caused a neurological condition known as TARDIVE DYSKINESIA.” (*Id.* at 2.) Plaintiff

brought his action based on diversity of citizenship jurisdiction, 28 U.S.C. § 1332,¹ noting that he was a resident of Michigan and Defendant AstraZeneca was incorporated in Delaware. (Doc. 4 at 2.) Plaintiff explained that he filed his suit in Florida because “all federal Astrazeneca lawsuits have been consolidated in a Multidistrict Litigation centralized in” that court. (Doc. 1 at 1.)

On December 13, 2011, Defendant AstraZeneca filed its answer to the complaint. (Doc. 5 at 2 (Case No. 12-00081, docket entry #7).)

On January 24, 2012, the Western District of Florida transferred Plaintiff’s case to the Western District of Michigan because Plaintiff is incarcerated within the boundaries of that district.

On February 13, 2012, Plaintiff, without seeking the Court’s permission through a motion to amend, filed an “Amended Complaint for Negligence.” (Doc. 5 at 3 (W.D. Mich. Case No. 12-00081, docket entry #18).) Plaintiff purported to add Defendants Sandra Vonderembse and the Michigan Department of Corrections (“MDOC”) - Health Services, alleging that Dr. Vonderembse negligently prescribed the drug Seroquel without warning Plaintiff of the possible side effects and that the MDOC Health Services Division, as the doctor’s employer, was also liable for the doctor’s breach of the duty to warn of side effects. (Doc. 3 at 2.²)

On February 22, 2012, Defendant AstraZeneca filed a motion to dismiss, asserting that it is immune from suit pursuant to Michigan’s product liability statute because the drug in question was approved by the Federal Drug Administration. (Doc. 5 at 3 (W.D. Mich. Case No. 12-00081, docket entry #19).)

On March 8, 2012, the Western District transferred the case to this district because the events giving rise to the allegations occurred while Plaintiff was incarcerated at the Gus Harrison Correctional Facility in Adrian, Michigan, which is within the boundaries of the U.S. District

¹Section 1332 grants federal district courts original jurisdiction over civil actions in which the amount in controversy exceeds \$75,000.00 and the case is between citizens of different states or between citizens of a state and foreign nationals or sovereigns.

²The Amended Complaint for Negligence that was originally filed as Doc. 18 in the Western District is now Doc. 3 on the Eastern District’s docket.

Court for the Eastern District of Michigan. (Doc. 5 at 3 (W.D. Mich. Case No. 12-00081, docket entry #27)³.) The Amended Complaint was apparently considered to be the operative pleading and thus Sandra Vonderembse and MDOC - Health Services were listed on the docket as defendants.

On April 6, 2012, Plaintiff filed a response in opposition to Defendant AstraZeneca's motion to dismiss. (Doc. 10.) Since the motion had not been entered on this Court's docket, Defendant AstraZeneca re-filed its motion to dismiss on April 12, 2012 (Doc. 12), and subsequently filed a reply. (Doc. 15.)

On April 16, 2012, the case was referred to the undersigned magistrate judge for all pretrial proceedings pursuant to 28 U.S.C. § 636(b)(1). (Doc. 13.) After screening the case pursuant to 28 U.S.C. § 1915(e)(2)(B) and considering the pending motion papers, I conclude that a Report and Recommendation is warranted.

B. Diversity Jurisdiction

Plaintiff explicitly states in both his original and amended complaints that he is bringing his claims of negligence in federal court on the basis of diversity jurisdiction. Federal law provides that diversity jurisdiction arises when the matter is between citizens of different states and the amount in controversy exceeds \$75,000. 28 U.S.C. § 1332. It has long been settled that this statute requires "complete diversity" of citizenship between the parties. *See City of Indianapolis v. Chase Nat'l Bank*, 314 U.S. 63, 69-70, 62 S. Ct. 15, 86 L. Ed. 47 (1941). "Complete diversity" means that no party shares citizenship with any opposing party. *Safeco Ins. Co. of America v. City of White House, Tenn.* 36 F. 3d 540, 545 (6th Cir. 1994).

C. The Amended Complaint

Rule 15 of the Federal Rules of Civil Procedure governs the filing of an amended complaint. It provides that "[a] party may amend its pleading once as a matter of course within: (A) 21 days after serving it, or (B) if the pleading is one to which a responsive pleading is required, 21 days

³The Order of Transfer that was originally filed as Doc. 27 in the Western District is now Doc. 4 on the Eastern District's docket.

after service of a responsive pleading or 21 days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier.” Fed. R. Civ. P. 15(a)(1). In this case, the complaint was filed on November 11, 2011 (Doc. 1), Defendant AstraZeneca filed its answer to the complaint on December 13, 2011 (Doc. 5 at 2 (Case No. 12-00081, docket entry #7)), and Plaintiff filed his amended complaint on February 13, 2012. (Doc. 5 at 3 (Case No. 12-00081, docket entry #18).) Pursuant to Rule 15(a)(1), however, Plaintiff’s deadline for amending as a matter of course was January 3, 2012, which was 21 days after service of AstraZeneca’s responsive pleading.

If a party does not meet the deadline for amending as a matter of course that is imposed by Rule 15(a)(1), Rule 15(a)(2) applies, which provides that, “[i]n all other cases, a party may amend its pleading only with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). In this case, the record is clear that Plaintiff did not file a motion for leave to amend and there is no record that Plaintiff obtained AstraZeneca’s written consent to amend. Accordingly, I suggest that, at this stage of the case, the original complaint is the operative pleading and the amended complaint, which was filed more than one month after the deadline for amending as a matter of course and which named the non-diverse parties of Sandra Vonderembse and the MDOC Health Services Division, has no effect.

D. Defendant AstraZeneca’s Motion to Dismiss

1. Standard of Review

In facing a motion to dismiss for failure to state a claim under Rule 12(b)(6) of the Federal Rules of Civil Procedure, “[t]he court must construe the complaint in the light most favorable to the plaintiff, accept all the factual allegations as true, and determine whether the plaintiff can prove a set of facts in support of its claims that would entitle it to relief.” *Bovee v. Coopers & Lybrand C.P.A.*, 272 F.3d 356, 360 (6th Cir. 2001). As the Supreme Court held in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007), a complaint must be dismissed pursuant to Rule 12(b)(6) for failure to state a claim upon which relief can be granted if the

complaint does not plead “enough facts to state a claim to relief that is plausible on its face.” *Id.* at 570 (rejecting the traditional Rule 12(b)(6) standard set forth in *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957)).

Under Rule 12(b)(6), “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitlement to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (citations omitted). Even though a complaint need not contain “detailed” factual allegations, its “[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” *Id.* (citations omitted).

2. Parties’ Arguments

Plaintiff claims that Defendant AstraZeneca “negligently had a product on the market, a drug known as SEROQUEL, which caused the plaintiff . . . to develop irreversible side effects, and caused a neurological condition known as TARDIVE DYSKINESIA.” (Compl., Doc. 1 at 2.) Defendant AstraZeneca characterizes this allegation as a products liability claim (Mot. to Dismiss, Doc. 12, Br. at 1), and asserts that it must be dismissed pursuant to the Michigan statute, Mich. Comp. Laws § 600.2946(5), that provides immunity for product liability claims against manufacturers of FDA-approved products. (Doc. 12, Br. at 3.) Defendant states that Seroquel is an “atypical antipsychotic prescription drug, first approved by the FDA for the treatment of schizophrenia in 1997.” (Doc. 12, Br. in Supp. at 1.)

Plaintiff disagrees with Defendant’s characterization of his claim as a products liability claim. (Response, Doc. 10 at 3.) Plaintiff emphatically states that this is “NOT a product liability claim,” explaining that he “filed the complaint as a negligence complaint because after a multitude of State and Federal Lawsuits, ASTRAZENECA L.P. has continued to keep SEROQUEL on the market with total disregard to safety, and total disregard to the injuries it is causing consumers to suffer.” (*Id.*) Plaintiff further argues that, despite having knowledge of the injuries caused by

Seroquel, Defendant keeps Seroquel on the market “in order to gain a financial profit,” which Plaintiff asserts “falls well within the elements of negligence.” (*Id.* at 4.)

Plaintiff further asserts that AstraZeneca is not entitled to the immunity granted by the Michigan statute because Plaintiff “believes there is evidence” that AstraZeneca “falsely promoted the drug SEROQUEL in order to gain approval from the F.D.A.,” but the information is not available in the prison law library. (Doc. 10 at 3.) Further, Plaintiff claims that he is “aware of ongoing litigation” between the U.S. Department of Justice and AstraZeneca regarding false promotion of the drug, but again, the information is not available to Plaintiff due to his incarceration. (*Id.*)

Defendant AstraZeneca replies that it does not matter what label a plaintiff chooses to place on his claim, the substance of the claim controls and in this case the substance of Plaintiff’s claim squarely fits the definition of a products liability suit under Michigan law. (Doc. 15 at 2.) Further, Defendant replies that Plaintiff’s contention that he believes AstraZeneca falsely promoted the drug and is in litigation over such promotion is irrelevant, because in order to meet the exception for the application of the immunity statute, a plaintiff must establish that the FDA itself has found that the drug manufacturer either committed fraud against the FDA or bribed an FDA official, neither of which is alleged, or could be alleged, by Plaintiff. (*Id.*)

3. Analysis and Conclusions

I first suggest that Plaintiff’s complaint asserts a products liability claim under Michigan law. As Defendant AstraZeneca points out, in Michigan, a “product liability action” is “an action based on a legal or equitable theory of liability brought for . . . injury to a person . . . caused by or resulting from the production of a product.” Mich. Comp. Laws § 600.2945(h). “Production” includes, among other things, the formulation, manufacture, and sale of a product. Mich. Comp. Laws § 600.2945(i). “Thus, under Michigan’s statutory scheme, a suit against a drug manufacturer for injury or death related to the drug is a product liability suit when the plaintiff alleges fault in the standards, testing, warning, instruction, marketing, selling, advertising or labeling of the drug.”

White v. SmithKline Beecham Corp., 538 F. Supp. 2d 1023, 1027 (W.D. Mich. 2008). Here, where Plaintiff alleges under the “legal theory” of negligence that Defendant AstraZeneca manufactured, sold, and continues to sell a drug that injured him, it is clear that his complaint asserts a product liability action.

I next suggest that Defendant is correct that Michigan’s product liability statute concerning pharmaceuticals creates broad immunity for pharmaceutical manufacturers. With two limited exceptions, the statute provides that

a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration approval at the time the drug left the control of the manufacturer or seller.

Mich. Comp. Laws § 600.2946(5). This liability protection does not apply if the defendant

(a) [i]ntentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted [to the FDA] . . . and the drug would not have been approved or the [FDA] would have withdrawn approval if the information were accurately submitted [or]

(b) [m]akes an illegal payment to an official or employee of the [FDA] for the purpose of securing or maintaining approval of the drug.

Id.

Plaintiff has not alleged that Seroquel was not “approved for safety and efficacy” by the FDA or that the labeling was not in compliance with FDA approval at the time it left Defendant’s control. Therefore, the statute provides immunity to Defendant AstraZeneca as the manufacturer of the drug unless Plaintiff can show that one of the exceptions applies. To that end, Plaintiff asserts that he “believes there is evidence” that AstraZeneca “falsely promoted the drug SEROQUEL in order to gain approval from the F.D.A.,” and believes that there is “ongoing litigation” between the U.S. Department of Justice and AstraZeneca regarding Seroquel. (Doc. 10 at 3.) However, even if both of Plaintiff’s beliefs are correct, Defendant’s statutory immunity would not be overridden because the Sixth Circuit has held that, in order for the exception to be met, the FDA itself must have found that the defendant manufacturer committed fraud or bribery

in the process of obtaining FDA approval. *See Blair v. Genentech, Inc.*, No. 1:11-CV-482, 2011 WL 5088969, at *5 (W.D. Mich. Oct. 26, 2011) (“For the exceptions to apply, there must have been a federal determination of fraud on the agency.”); *Ammend v. BioPort, Inc.*, No. 5:03-CV-31, 2006 WL 1050509, at *3 (W.D. Mich. April 19, 2006) (“a plaintiff may not establish the exceptions through proof of fraud or bribery, but instead must show that the FDA has made its own determination of fraud or bribery”) (citing *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004)).

Accordingly, because Michigan’s products liability statute immunizes Defendant AstraZeneca from liability, I suggest that Defendant’s motion to dismiss for failure to state a claim be granted and, since AstraZeneca is the sole defendant, that the case be dismissed in its entirety.

E. Allowing Amendment to Add Dr. Vonderembse & MDOC Would Be Futile

In his purported “Amended Complaint for Negligence,” Plaintiff alleged that Dr. Vonderembse was negligent when she breached her duty to warn Plaintiff of the possible side effects of the drug Seroquel. (Doc. 3 at 2.) Claims alleging negligence against prison medical personnel, however, do not state a federal claim. Allegations of negligence against a doctor, which are also known as “medical malpractice” claims, are addressed under state law by the state courts. The United States Supreme Court has long held that “[m]edical malpractice does not become a constitutional violation merely because the victim is a prisoner.” *Estelle v. Gamble*, 429 U.S. 97, 106, 97 S. Ct. 285, 50 L. Ed. 2d 251 (1976).

Here, where Plaintiff sought to add a claim against Dr. Vonderembse alleging negligence for failure to warn Plaintiff about the possible side effects of a drug, he has alleged a state law medical malpractice claim over which this Court would have no jurisdiction, since there is no “federal question” and no diversity of citizenship.

Furthermore, I suggest that Plaintiff’s purported allegation against the Michigan Department of Corrections (“MDOC”) or its Health Services Division fails to state a claim because it has long

been established that, regardless of the form of relief requested, the states and their departments are immune under the Eleventh Amendment from suit in the federal courts if the state has not waived immunity and Congress has not expressly abrogated Eleventh Amendment immunity by statute. *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 98-101, 104 S. Ct. 900, 79 L. Ed. 2d 67 (1984); *Alabama v. Pugh*, 438 U.S. 781, 782, 98 S. Ct. 3057, 57 L. Ed. 2d 1114 (1978); *Sims v. Michigan Dep't of Corrections*, 23 Fed. Appx. 214, 215 (6th Cir. 2001); *O'Hara v. Wigginton*, 24 F.3d 823, 826 (6th Cir. 1993). Congress has not expressly abrogated Eleventh Amendment immunity by statute, *Quern v. Jordan*, 440 U.S. 332, 341, 99 S. Ct. 1139, 59 L. Ed. 2d 358 (1979), and the state of Michigan has not consented to civil rights suits in federal court. *Abick v. Michigan*, 803 F.2d 874, 877 (6th Cir. 1986).

Accordingly, I suggest that Plaintiff should not be allowed to amend his complaint to add the claims he attempted to assert through his improperly filed Amended Complaint for Negligence, because this Court would have no subject matter jurisdiction over the claim against Dr. Vonderembse and the MDOC is immune from suit; therefore, the amendment would be futile.

III. REVIEW

Pursuant to Rule 72(b)(2) of the Federal Rules of Civil Procedure, “[w]ithin 14 days after being served with a copy of the recommended disposition, a party may serve and file specific written objections to the proposed findings and recommendations. A party may respond to another party’s objections within 14 days after being served with a copy.” Fed. R. Civ. P. 72(b)(2). *See also* 28 U.S.C. § 636(b)(1). Failure to file specific objections constitutes a waiver of any further right of appeal. *Thomas v. Arn*, 474 U.S. 140, 106 S. Ct. 466, 88 L. Ed.2d 435 (1985); *Howard v. Sec’y of Health & Human Servs.*, 932 F.2d 505 (6th Cir. 1991); *United States v. Walters*, 638 F.2d 947 (6th Cir. 1981). The parties are advised that making some objections, but failing to raise others, will not preserve all the objections a party may have to this Report and Recommendation.

Willis v. Sec'y of Health & Human Servs., 931 F.2d 390, 401 (6th Cir. 1991); *Smith v. Detroit Fed'n of Teachers Local 231*, 829 F.2d 1370, 1373 (6th Cir. 1987). Pursuant to E.D. Mich. LR 72.1(d)(2), a copy of any objections is to be served upon this magistrate judge.

s/ Charles E Binder
CHARLES E. BINDER
United States Magistrate Judge

Dated: May 22, 2012

CERTIFICATION

I hereby certify that this Report and Recommendation was electronically filed this date, electronically served on Jill Wheaton, and Mark Magyar; and served by first class mail on Aubrey Lee Christian, #722265, Lakeland Correctional Facility, 141 First St., Coldwater, MI, 49036.

Date: May 22, 2012

By s/Jean L. Broucek
Case Manager to Magistrate Judge Binder